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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,443	08/30/2001	Jean-Christophe Audonnet	454313-2220.1	9956
20999	7590	06/27/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/943,443	<b>Applicant(s)</b> AUDONNET ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/232,278.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicant's amendment filed April 6, 2005 is acknowledged and entered. Claims 11-25 are pending. Claims 11-20 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 21-25 are under examination.

### ***Response to Amendment***

2. In view of Applicant's amendments, the following objection and rejections are withdrawn:

- The objection to claim 24 for a misspelling is withdrawn in view of Applicant's amendment correcting the spelling of cytomegalovirus and spelling out the CMV-IE acronym.
- The rejection of claims 21-25 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendment clarifying the method steps. In light of the clarified method steps, one of skill in the art would know what types of cells are capable of being infected with feline immunodeficiency virus (CD4<sup>+</sup> and CD8<sup>+</sup> T-cells).
- The rejection of claims 21-25 under 35 U.S.C. 112, second paragraph, for reciting incomplete method steps is withdrawn. According to amended method steps, the method of inducing an immune response is clear.

### ***Claim Rejections - 35 USC § 102 – Response to Applicant's Arguments***

3. Claims 21, 24 and 25 remain rejected under 35 U.S.C. 102(a) as being anticipated by Wardley *et al.* (WO95/30019, "Wardley") for reasons of record. The claims are drawn to a

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method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering to a feline host at least one plasmid, wherein the plasmid contains and expresses in vivo in a feline host cell nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. The method further comprises administering a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen. The plasmid further comprises a cytomegalovirus early promoter. (Since the claims do not recite method steps, the claims have been broadly interpreted to be any method of inducing an immune response that uses a plasmid encoding the appropriate FIV genes.) Wardley teaches a method of inducing an immune response in felines by administering a recombinant feline herpes virus vector containing DNA encoding FIV gag and env proteins (Wardley, abstract and claim 11). The FIV DNA of env and gag are inserted into transfer vectors/plasmids, and CMV early promoter is used (pages 7-8, bridging paragraph, and page 13, lines 22-23). Therefore, the claims remain anticipated by Wardley.

Applicant's arguments have been fully considered but fail to persuade. Applicant's substantive argument is primarily directed to the assertion that Wardley fails to anticipate the invention as amended. Applicant argues that Wardley relates to viral vectors containing plasmids, but does not teach the use of the plasmid itself in the making of the vaccines. In response to these arguments, the Office interprets the claim with reasonable broadness. In the instant case, the claims read on a method **comprising** administering at least one plasmid. Given the open claim language, the claims reasonably read on the administration of a plasmid in

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addition to anything else. Wardley administers a plasmid in a vector, thus reading on the instant invention. The claims do not specify that the plasmid is naked. Therefore, since the claims are broadly written, they remain anticipated by Wardley.

***Claim Rejections - 35 USC § 103***

4. Claims 22, 23 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wardley as applied to claims 21, 24 and 25 above, and further in view of Mazzara *et al.* (U.S. Patent 5,804,196, "Mazzara"). The claims are drawn to a method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising administering at least one plasmid, wherein the plasmid contains and expresses *in vivo* in a feline host cell nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. The method further comprises administering a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen. The teachings of Wardley are summarized above. Wardley is silent on the use of the protease (pro) gene of FIV. However, Mazzara discloses a recombinant fowlpox viral vector that expresses the env, gag and pol genes of lentiviruses such as HIV, FIV or SIV (col. 3, lines 37-46). Mazzara also teaches that the vector can be administered with live recombinant viruses (col. 8, lines 45-50). It would have been obvious to incorporate the pol gene, which contains the pro gene, into Wardley's vector because pol protein (pro protein) is capable of eliciting an immune response (col. 8, lines 39-44). One would have had a reasonable expectation of success that a vector that contains env, gag and pol (pro) would have induced an

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immune response, because Mazzara's vector contains env, gag and pol (pro) and elicits an immune response. It would have also been obvious to administer Wardley's vector with a live recombinant virus because Mazzara teaches the co-administration of the vector and live recombinant virus for a total vaccination protocol (col. 8, lines 45-50). One would have had a reasonable expectation of success that the administration of both the vector and a live recombinant virus would have induced an immune response because both elements are separately capable of inducing an immune response. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but fail to persuade. Applicant's substantive argument is primarily directed to the assertion that Mazzara fails to remedy the deficiencies of Wardley. Applicant argues that Mazzara relates to viral vectors containing plasmids, but does not teach the use of the plasmid itself in the making of the vaccines. In response to these arguments, the Office interprets the claim with reasonable broadness. In the instant case, the claims read on a method **comprising** administering at least one plasmid. Given the open claim language, the claims reasonably read on the administration of a plasmid in addition to anything else. Contrary to Applicant's assertion, Wardley's supposed deficiency is not a deficiency. Wardley administers a plasmid in a vector, thus reading on the instant invention. The claims do not specify that the plasmid is naked. Therefore, since the claims are broadly written, they remain obvious over Wardley in view of Mazzara.

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***Conclusion***

5. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*SBC*

Stacy B. Chen  
June 22, 2005

*James C. Housel*  
*6/24/05*

JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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